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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,498	06/01/2001	Adilson Leite	FAPESP 203	8814

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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	**PAPER NUMBER**
1657	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/870,498	LEITE ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,17-28 and 30* is/are pending in the application.

4a) Of the above claim(s) *1-4,8 and 17-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/07/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Response and amendment filed 06 August 2007 in response to Office Action mailed 03 May 2007 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

2. The information requested in Points 5 and 6 of the Office Action mailed 03 May 2007 are important and pertinent to entire prosecution of instant application, because application information and correct location where said application is being prosecuted at the USPTO are fundamental to receiving timely communication at the USPTO and responding to applicants' response in said application.

3. Remarks in regard to Interview Summary of the telephone interview of 06 February 2007 and status of Claims 1-4 and 17-28 in the response filed 07 February 2007 are not germane because status for Claims 1-4 and 17-28 is correctly indicated in response filed 06 August 2007.

Claim Status

4. Claim 30 has been added.

5. Claims 9-16 and 29 have been cancelled.

6. Claim 6 has currently been amended.

7. Claims 1-8 and 17-28 are pending.

8. Claims 1-4, 8 and 17-28 have been withdrawn.

9. Claims 5-7 and newly presented Claim 30 are examined on merits.

10. Please note that status for Claim 8 as presented in the amendment and response filed 06 August is confusing because in the Claims Listing, Claim 8 is indicated as "withdrawn". In remarks, however, the statement is that Claim 8 is "canceled"(See Remarks filed 06 August, Page 6, Line 26).

Claim Rejections - 35 U.S.C. §112, First Paragraph

11. Claims 5-7, and newly presented Claim 30 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was

not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Said Claims are also rejected as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with those claims.

In response to rejection cited *supra,* the argument presented is that the rejection is confusing. However, there is no explanation of what is unclear or confusing about the rejection.. The rejection is about the written description and enabling one of skill to practice the claimed invention commensurate in scope with the claims as currently presented. A further argument is, "Examiner seeks to limit claims to SEQ ID NO: 1, failing to recognize that SEQ ID figure 1 delineates 14 peptides all of which satisfy the dictates of Claim 5. The Examiner is invited to review the discussion of figure 1 in the specification, and figure 1 itself".

In the instant case, the claims as presented in the amendments filed 06 August 2007 are drawn to the genus of an isolated antimicrobial peptide consisting of from 10 to about 50 amino acids, wherein said peptide genus comprises 10 to about 12 continuous amino acids, wherein a given number of those contiguous amino acids are hydrophobic residues, at least one a histidine, glutamic acid or serine with the proviso that two of the hydrophobic amino acids are adjacent tryptophans. The isolated peptide comprises amino acid sequence set forth in SEQ. ID number 1-14.

Figure 1 as currently presented shows and the description thereof discusses 14 different peptides, however, only sequences 1-4 meet the criteria of "10 to about 50 amino acids" because each of the other 10 sequences show only 7 amino acids. Please note that aside from that, they also do not meet all the criteria mentioned in Claim 5.

Applicants' arguments cited *supra* have been fully and carefully considered, but are not persuasive for the reasons of record at Page 4-9, items 13-16 of the Office Action mailed 03 May 2007 and further because of the reasons explained in the preceding paragraph. Accordingly, the rejection of Claims 5-7 and 30 is maintained and adhered to.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 5 is rejected under 35 U.S.C. §102(b) as anticipated by Travis et al (US Patent 5,447,914).

Claim 5 recites an isolated antimicrobial peptide consisting of from 10 to about 50 amino acids, wherein said peptide genus comprises 10 to about 12 continuous amino acids, wherein a given number of those contiguous amino acids are hydrophobic residues, at least one a histidine, glutamic acid or serine with the proviso that two of the hydrophobic amino acids are adjacent tryptophans.

Regarding Claim 5, Travis et al. teach a peptide comprising 20 amino acids. Said peptide comprises 10-12 contiguous amino acids, wherein at least 11 of those amino acids are hydrophobic, at last 3 are basic, at least one histidine, and/ or serine and two of hydrophobic amino acids are adjacent to tryptophan (See Abstract, Line 6). Thus, Travis et al. teach an isolated peptide having each of the limitations that the instantly Claim 5 has. Thus, the prior art isolated peptide inherently is an anti microbial peptide because it is comprised of the same amino acid constituents as is instantly claimed (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claim.

14. Claims 5-6 and 30 are rejected under 35 U.S.C. § 102(b) as anticipated by Little et al. (WO 00/18951) with evidence provided by Charles S. Gasser (1996, U. C. Davis, Biological Sciences, Amino Acid Properties. Printed from http://www.mcb.ucdavis.edu/courses/bis 102/AAProp.html on 25 October 2007).

Claims 5-6 and 30 recite an isolated antimicrobial peptide consisting of from 10 to about 50 amino acids, wherein said peptide genus comprises 10 to about 12 continuous amino acids, wherein 7 of those contiguous amino acids are hydrophobic residues, at least one a histidine, glutamic acid or serine with the proviso that two of the hydrophobic amino acids are adjacent tryptophans. Said isolated antimicrobial peptide comprises the amino acid sequence set forth in SEQ. ID No:1.

- Regarding Claims 5-6 and 30, Little et al. teach an antimicrobial peptide having:
- amino acid sequence as set forth in SEQ. ID No:1 (Page 8, Lines 25-26);
- comprising of 10-50 amino acids;
- wherein said peptide comprises 10-12 contiguous amino acids;
- at least 11 of those amino acids are hydrophobic;

- at least 3 amino acids are basic;
- said peptide further comprises at least one histidine; and
- two of hydrophobic amino acids are adjacent to tryptophan (See Example 1 at Page 26, Figure 1 and Sequence Listing labelled <400> 1 at Sheet 1 of 2).

Note that said sequence comprises 12 contiguous amino acids, at least seven (namely, Val, Gly,Trp, Leu (2 residues), Ile and Phe) of which are hydrophobic (See Gasser 1996, Line 3), three (i.e., Lys) are basic (See Gasser 1996, Line 7), two (i.e., Gly and Leu) are adjacent to tryptophan (Trp) and additionally has at least one histidine (i.e., His). Thus, Little et al. teach an isolated antimicrobial peptide having a sequence as set forth in SEQ. ID No:1 and additionally having each of the limitations described in instant Claims 5-6 and 30.

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 U.S.C. §103

15. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § *102*(f) or (g) prior art under 35 U.S.C.§ 103(a).

17. Claims 5-7 and 30 are rejected under 35 U.S.C. § 103 (a) as obvious over the combined teachings from Travis et al (US Patent 5,447,914) in view of Little et al. (WO 00/18951) with evidence provided by Charles S. Gasser (1996, U. C. Davis, Biological Sciences, Amino Acid Properties. Printed from http://www.mcb.ucdavis.edu/courses/bis 102/AAProp.html on 25 October 2007) and further in view of Aley et al (Infection and Immunity, 1994, Volume 62, pages 5397-5403).

Claims recite an isolated antimicrobial amidated, carboxymethylated or cyclized antimirobial peptide comprising up to 50 amino acid residues, wherein said peptide is comprised of 10-12 contiguous amino acids of which 7 are hydrophobic, 3 are basic and at least one is one among histidine, glutamic acid

or serine with two of the hydrophobic residues comprised of adjacent tryptophan residues. Additionally said peptide comprises amino acid sequence as set forth in SEQ ID NO: 1.

Teachings from each of Travis et al. and Little et al. with evidence provided by Charles S. Gasser have been discussed in items 15-16 *supra.*

Travis et al., however, do not explain that said isolated peptide is amidated, carboxymethylated or cyclized.

Aley et al. teach isolated antimicrobial polypeptide, i.e., defensins and indolicidins that have nine highly conserved amino acid residues (Page 5397, Column 1, Lines 38-43) are uniquely tryptophan rich (Abstract Lines 15-16) and additionally comprises C-terminal amide (Page 5397, Column 2, Lines 31-34). Aley et al. further teach that said polypeptides have conservative substitutions and also have amphipathic surface topology (Page 5400, Column 2, below Figure 4, Lines 5-15).

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Travis et al. with those from Little et al. and Aley et al's to obtain the claimed amidated, carboxymethylated or cyclized antimicrobial peptide having the amino acid sequence of SEQ ID NO: 1, wherein said antimicrobial peptide is comprised of 10-12 contiguous amino acids of which 7 are hydrophobic, 3 are basic and at least one is one among histidine, glutamic acid or serine with two of the hydrophobic residues comprised of adjacent tryptophan residues, additionally said peptide comprising amino acid sequence as set forth in SEQ ID NO: 1 and further comprised of 10-12 contiguous amino acids of which 7 are hydrophobic, 3 are basic and at least one is one among histidine, glutamic acid or serine with two of the hydrophobic residues comprised of adjacent tryptophan residues. Additionally said peptide comprises amino acid sequence as set forth in SEQ ID NO: 1 because, Little et al. teach a n antimicrobial peptide having identifying sequence of SEQ. ID No: 1 and additionally comprised of comprised of 10-12 contiguous amino acids of which 7 are hydrophobic, 3 are basic and at least one is one among histidine, glutamic acid or serine with two of the hydrophobic residues comprised of adjacent tryptophan residues, while Aley et al. teach amidated, carboxymethylated, or cyclized antimicrobial peptide.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Travis et al's teachings with those from Little et al., and Aley et al's to obtain the claimed antimicrobial, polypeptide having the amino acid sequence of SEQ ID NO: 1; because Little et al., teach an antimicrobial polypeptide having the amino acid sequence of SEQ ID NO: 1 comprised of same hydrophobic and basic amino acid residues and further having same structure function

relationships as well as substitutions, while Aley et al. teach that defensins and indolicidins are isolated antimicrobial peptides rich in tryptophan, have at least 9 highly conservative amino acid residues and amidated c-terminus.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

18. For aforementioned reasons, no Claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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October 29, 2007

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